General Requirements for Informed Consent: The "informed consent" process incorporates three key features: (1) disclosing to potential research subjects information needed to enable them to make an informed decision about whether to participate in the research; (2) facilitating the potential subject's understanding of the information disclosed; and (3) promoting the fact that it is entirely voluntary for the subject whether or not to participate in the study, both before and during the study.

For the purposes of human research, the basic elements of information necessary to be given before such legally effective informed consent can be attained shall include:

a. a statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject's participation; a description of the procedures or protocols to be followed; identification of any procedures that are experimental; and, where applicable, disclosure of the approximate number of subjects involved in the study;

b. a description of any reasonably foreseeable risks or discomforts to the subject and a statement that there may be other risks not yet identified;

c. a description of any benefits to the subject or to others that may reasonably be expected from the research, and a statement that all significant new findings developed during the course of the research that may be related to the subject's willingness to continue to participate will be provided to the subject;

d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; also, that if any data from the study are published, a statement that the subject will not be identified without the subject's written permission;

f. for research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained;

g. an explanation of any costs or compensation which may accrue to the subject and, if applicable, the availability of third-party reimbursement for the proposed procedures or protocols;

h. an offer to answer any inquiries by the subject concerning the procedures and protocols, and an explanation of whom to contact for answers to pertinent questions about the research and the subjects' rights; also, whom to contact in the event of a research-related injury to the subject;

i. a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may withdraw his consent and discontinue participation at any time, without prejudice;

j. where applicable, disclosure of the consequences of a subject's decision to withdraw from the research and the procedures for an orderly termination of the subject's participation; and

k. where applicable, any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

The IRB may approve a consent procedure that does not include, or alters, some or all of the elements of informed consent set forth above. It may waive the requirement to obtain informed consent, provided the IRB finds and documents that:

a. the research involves no more than minimal risk to the subjects;

b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. the research could not practicably be carried out without the waiver or alteration; and

d. the subjects will be provided with additional pertinent information after participation, as appropriate.